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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/574,133

11/13/2006

Siddhartha Sikdar

UNIV0350

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08/19/2009

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EXAMINER

BRUTUS, JOEL F

ART UNIT

PAPER NUMBER

3768

MAIL DATE

DELIVERY MODE

08/19/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/574,133	<b>Applicant(s)</b> SIKDAR ET AL.	
	<b>Examiner</b> JOEL F. BRUTUS	<b>Art Unit</b> 3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 13 November 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) 1-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 19-28 and 33-39 is/are rejected.
- 7) ☒ Claim(s) 29-32 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 March 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1/6/2009, 4/25/2008, 6/1/2007 and 6/26/2006</u> .             | 6) <input type="checkbox"/> Other: _____                          |



**DETAILED ACTION**

***Election/Restrictions***

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-17, drawn to a method for detecting internal bleeding using processed data.

Group II, claim(s) 19-39, drawn to an apparatus for detecting internal bleeding.

The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Group II claims 19-39 is a product that can be used for imaging, therapeutic etc... and whereas Group I claims 1-18 is a process of ultrasound signal. The product can be used for purposes other than signal processing.

2. Applicant's election with traverse of group II claims 19-39 via a phone on 8/3/2009 is acknowledged. The traversal is on the ground(s) that no arguments were presented. This is not found persuasive because Applicant doesn't give a reason to traverse.

The requirement is still deemed proper and is therefore made FINAL.

***Claim Objections***

3. Claim 19 is objected to because of the following informalities: --an-- should have been in front of apparatus in line 1 of the preamble. Appropriate correction is required.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 19-28 and 33-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lin (US Pat: 5,919,139) stand alone.

Regarding claims 19-23, Lin teaches a system for performing vibrational Doppler ultrasonic imaging that is pertinent to the claimed invention. Lin teaches a vibrational wave of a first frequency is introduced into an area of a subject to be scanned. An ultrasound signal is simultaneously introduced into the area. The vibrational wave is of a sufficient frequency and amplitude to induce palpable vibrations in the tissue medium of the area being scanned. An ultrasonic Doppler imaging system detects these tissue vibrations and processes the resulting scanned data for display on a display device. To examine internal body structures, ultrasonic images are formed by producing very short pulses of ultrasound using a transducer, sending the pulses through the body, and

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measuring the properties of the echoes (e.g., amplitude and phase) from tissues within the body. Typically, the ultrasound beam is focused at various steps within the body to improve resolution or image quality. Echoes are received by the transducer and processed to generate an image of the object. The resulting image is usually referred to as a B-scan image [see column 1 lines 16-24].

Lin teaches in FIG. an imaging system 100 that comprises a probe 101, which is typically a multi-element array of piezoelectric elements which both send and receive ultrasound signals when examining a subject, such as a living patient. Probe 101 is coupled via signal path 110 to transmitter/receiver circuitry which is coupled to a control unit 109 via bus 120 and is controlled so that the elements in probe 101 are focused at particular points in the body during both transmission and reception of ultrasound signals. Transmitter/receiver circuitry 102 and control unit 109 also often provide a scanning function so that a two-dimensional image may be generated without moving probe 101 with respect to the body [see column 3 lines 40-56].

An ultrasonic imaging device using an audio frequency vibrational source is disclosed. A first transducer transmits vibrational energy of a first frequency into an area of a subject to be scanned. An ultrasound transducer transmits ultrasound pulses into the area. The vibrational energy transmitted by the first transducer induces palpable vibrations in the tissue medium of the area being scanned. The amplitude and frequency variance of these vibrations reflect certain mechanical properties, such as elasticity, inertia, resonance, and vibration damping properties of the tissue [see column 2 lines 21-30]. The first transducer includes an audio speaker and is connected to a

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variable frequency tone generator that produces audio waveforms which are converted to vibrational energy by the speaker. An ultrasonic color Doppler imaging system connected to the ultrasound transducer processes the received imaging data from the ultrasound probe for display on a video monitor. The imaging system combines amplitude and variance data to generate a signal indicative of the magnitude and frequency variability of the vibrations induced by the audio transducer [see column 2 lines 32-46].

Lin doesn't specifically mention that the system is used to detect internal bleeding.

However, Lin teaches ultrasonic imaging technology has become a vital tool for examining the internal structure of living organisms. For the diagnosis of various medical conditions, ultrasonic imaging is often useful to examine soft tissues within the body to show the structural detail of internal tissues and fluid flow [see column 1 lines 10-15].

Therefore, one with ordinary skill in the art at the time the invention was made would have been motivated to modify the Lin reference by using the system to detect internal bleeding; for the purpose of diagnosing hemorrhages in order to prescribe the best possible treatment.

Regarding claims 33-39, all other limitations are taught as set forth by the above teaching.

Lin doesn't specifically mention bleeding site.

However, Lin teaches an audio-frequency tone is introduced into the medium or tissue to be scanned. The tone is of sufficient amplitude to induce palpable vibrations in the medium or tissue to be scanned, and can be detected by a conventional ultrasonic color Doppler imaging apparatus. Doppler signal processing is modified to reduce gain, discard frequency-shift data, and combine amplitude and/or variance data to generate a signal indicative of the magnitude and velocity range of the vibrations. This data is mapped according to a gray or color scale into two-dimensional image space [see column 4 lines 62-67 and column 5 lines 1-10].

Because the vibrations are continuous wave, the frequency of the traveling longitudinal wave is fixed. By bouncing ultrasonic waves off of the medium, Doppler signal processing detects frequency shifts in the returning echoes from moving acoustic reflectors within each volume element of the medium. Whenever a frequency shift is detected above a given threshold magnitude (e.g., by a high-pass filter generally set just above the low-frequency noise floor), motion is detected. Because frequency shifts alternate between positive and negative Doppler shifts at the rate of vibration, the temporally-averaged frequency shift signal cancels itself out, leaving only noise. However, the amplitude and variance signals are measures of the fractional volume of acoustic reflectors exceeding the given threshold Doppler shift and the range of variability [see column 5 lines 23-39].

Therefore, one with ordinary skill in the art at the time the invention was made would have been motivated to modify the Lin reference by using the system to detect



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internal bleeding; for the purpose of diagnosing hemorrhages in order to prescribe the best possible treatment.

Regarding claims 24-28, all other limitations are taught as set forth by the above teaching.

The above teaching is silent determine a bleeding rate.

However, Lin further teaches the present invention may be implemented in discrete hardware components or, alternatively, in programmed processing units such as digital signal processors using software which is compiled, linked and then loaded from disk-based storage for execution during run-time. Various programs containing the methods employed in these embodiments may also reside in firmware or other similar nonvolatile storage means [see column 3 lines 32-38].

Lin further teaches because frequency shifts alternate between positive and negative Doppler shifts at the rate of vibration, the temporally-averaged frequency shift signal cancels itself out, leaving only noise. However, the amplitude and variance signals are measures of the fractional volume of acoustic reflectors exceeding the given threshold Doppler shift and the range of variability [see column 5 lines 23-39].

Therefore, one with ordinary skill in the art at the time the invention was made would have been motivated to modify the Lin reference by determining a bleeding rate; in order to determine how intense the bleeding is occurring; thereby allowing medical practitioners to provide necessary treatment quicker.

***Allowable Subject Matter***

6. Claims 29-32 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The claims are allowable because none of the prior art of record does not teach nor fairly suggest a method for processing ultrasound data according to the claims comprising the steps of: estimating a mean clutter velocity from an ensemble of the ultrasound data, using autocorrelation; down mixing the ultrasound data with the mean clutter velocity, producing a down mixed signal; computing a phase of the down mixed signal and a mean phase of the down mixed signal; subtracting the mean phase from the phase of the down mixed signal, producing a residual phase; decomposing the residual phase into its dominant components; applying energy and frequency thresholds to the dominant components, to substantially suppress any contribution to the tissue vibration due to noise and blood flow, yielding an estimate of vibration amplitude and vibration frequency of tissue; and outputting an indication of the tissue vibration signal to a user in a format perceptible to the user.

***Conclusion***

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOEL F. BRUTUS whose telephone number is (571)270-3847. The examiner can normally be reached on Mon-Fri 7:30 AM to 5:00 PM (Off alternative Fri).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571)272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. F. B./  
Examiner, Art Unit 3768

/Long V Le/  
Supervisory Patent Examiner, Art Unit 3768